CLAIMS

1. An oral pharmaceutical dosage form comprising an acid susceptible proton pump inhibitor together with at least one Non Steroidal Antiinflammatory Drug (NSAID) and optionally pharmaceutically acceptable excipients, characterized in that the dosage form is in the form of a fixed unit dosage form comprising at least two pharmaceutically active components, and wherein at least the proton pump inhibitor is protected by an enteric coating layer.

2. A dosage form according to claim 1, wherein the dosage form is a tablet formulation.

3. A dosage form according to claim 1, wherein the dosage form is a capsule formulation.

4. A dosage form according to claim 1, wherein the proton pump inhibitor is protected by two layers, an enteric coating layer and a layer separating the enteric coating from the proton pump inhibitor.

5. A dosage form according to claim 1, wherein the dosage form comprises a proton pump inhibitor and one NSAID.

6. A dosage form according to claim 1, wherein the proton pump inhibitor is omeprazole, an alkaline salt thereof, one of its single enantiomer or an alkaline salt thereof.

7. A dosage form according to claim 6, wherein the proton pump inhibitor is S-omeprazole magnesium salt.

8. A dosage form according to claim 1, wherein the proton pump inhibitor is lansoprazole, or one of its single enantiomers or a pharmaceutically acceptable salt thereof.

9. A dosage form according to claim 1, wherein the proton pump inhibitor is pantoprazole, or one of its single enantiomers or a pharmaceutically acceptable salt thereof.

10. A dosage form according to one of claims 6 - 9, wherein the NSAID is ibuprofen, diclofenac, piroxicam or naproxen, or a pharmaceutical acceptable salt thereof.

11. A dosage form according to one of claims 6 - 9, wherein the ~~NSAID~~ is diclofenac or piroxicam, or pharmaceutically acceptable salt thereof.

12. A dosage form according to claim 1, wherein the amount of proton pump inhibitor is in the range of 10-80 mg and the amount of ~~NSAID~~(s) is in the range of 10-800 mg.

13. A dosage form according to claim 1, wherein the amount of proton pump inhibitor is in the range of 10-40 mg and the amount of NSAID(s) is in the range of 10-500 mg.

14. A tableted dosage form according to claim 2, wherein the tablet consists of two separate layers, one layer comprising a proton pump inhibitor and the other layer comprising one or more NSAIDs.

15. A tableted dosage form according to claim 2, wherein the tablet formulation is a multiple unit tableted dosage form comprising the proton pump inhibitor in the form of individually enteric coating layered pellets compressed together with NSAID comprising granules into a tablet, whereby the enteric coating layer covering the individual pellets has mechanical properties such that the tableting of the pellets together with the NSAID comprising granules and optionally pharmaceutically acceptable excipients does not significantly affect the acid resistance of the individually enteric coating layered pellets.

16. A tableted dosage form according to claim 15, wherein the acid resistance of the enteric coating layered pellets is in coherence with the requirements on enteric coating layered articles defined in the United States Pharmacopeia.

17. A tableted dosage form according to claim 15, wherein the acid resistance of the enteric coating layered pellets does not decrease more than 10 % during the compression of the pellets into the multiple unit tableted dosage form.

18. A tableted dosage form according to claim 15, wherein the enteric coating of the individual pellets comprises a plasticized enteric coating layer material.

19. A tableted dosage form according to claim 15, wherein the enteric coating layered pellets are further covered with an over-coating layer comprising pharmaceutically acceptable excipients.

20. A tableted dosage form according to claim 15, wherein the tablet is divisible.

21. A tableted dosage form according to claim 20, wherein the tablet is dispersible to an aqueous suspension comprising NSAID(s) and enteric coating layered pellets of a proton pump inhibitor.

22. A tablet dosage form according to claim 2, wherein the tablet consists of two separate layers, one layer comprising the proton pump inhibitor in the form of enteric coating layered pellets compressed with tablet excipients into a layer, and the other layer gives an extended release of the incorporated NSAID(s).

23. A tablet dosage form according to claim 22, wherein the layer comprising the NSAID(s) is a gelling matrix giving extended release.

24. A tableted dosage form according to claim 2, wherein the tablet is an enteric coating layered tablet comprising a mixture of the proton pump inhibitor and the NSAID comprising granules, optionally comprising a water soluble or in water rapidly disintegrating separating layer in between the tablet core and the enteric coating layer.

25. A tableted dosage form according to claim 2, wherein the tablet comprising enteric coating layered pellets of the proton pump inhibitor compressed into a tablet, which tablet is covered by a separate layer comprising the NSAID(s).

26. A tableted dosage form according to claim 25, wherein the tablet is covered by a pigmented tablet filmcoating layer.

27. A tablet dosage form according to claim 2, wherein the tablet consists of two types of enteric coating layered pellets, one type comprises the proton pump inhibitor, and the other type comprises NSAID(s), together compressed with tablet excipients into a tablet.

28. A tablet dosage form according to claim 2, wherein the tablet consists of enteric coating layered pellets comprising the proton pump inhibitor, and pellets comprising the NSAID(s) coating layered with an extended release film, and these coating layered pellets are compressed with tablet excipients into a tablet.

29. A process for the manufacture of a fixed dosage form comprising a proton pump inhibitor and one or more NSAIDs in a capsule, characterized in that the proton pump inhibitor is prepared in the form of enteric coating layered pellets and that the pellets are filled into a capsule together with prepared NSAID granules or enteric coating layered NSAID pellets, or NSAID pellets coating layered with an extended release film, optionally the mixture of pellets or granules are mixed with pharmaceutically acceptable excipients, and filled in a capsule.

30. A process for the manufacture of a fixed dosage form comprising a proton pump inhibitor and one or more NSAIDs in a multiple unit tableted dosage form, characterized in that the proton pump inhibitor is prepared in the form of enteric coating layered pellets and these pellets are mixed with prepared NSAID granules and optionally pharmaceutically acceptable tablets excipients whereafter the dry mixture is compressed into a multiple unit tablet without giving any significant change of the acid resistance of the enteric coating layer.

31. A process for the manufacture of a fixed dosage form comprising a proton pump inhibitor and one or more NSAIDs in a multiple unit tableted dosage form, characterized in that the proton pump inhibitor is prepared in the form of enteric coating layered pellets and the NSAID(s) is prepared in the form of coating layered pellets wherein the coating layer is an extended release layer or an enteric coating layer, and the prepared pellets are mixed with tablet excipients and compressed into a tablet.

32. A process for the manufacture of a fixed dosage form comprising a proton pump inhibitor and one or more NSAID(s) in an enteric coating layered tablet characterized in that the proton pump inhibitor is admixed with the NSAID(s) and pharmaceutically acceptable excipients whereafter the mixture is compressed into a tablet, and the tablet is covered with an enteric coating layer and optionally covered with a separating layer before the enteric coating layer is applied.

33. A method for the treatment of gastrointestinal side-effects associated with NSAID treatment in mammals and man by administering to a host in need thereof a therapeutically effective dose of a multiple unit tableted dosage form according to any of claims 1 to 28.

34. A method according to claim 33, wherein the disorder is an upper gastrointestinal disorder associated with NSAID treatment.

35. Use of a dosage form according to any of claims 1 to 28 for the manufacture of a medicament for treatment or prevention of gastro intestinal side-effects associated with NSAID(s) treatment disorders.

36. Use according to claim 35 wherein the disorder is an upper gastrointestinal disorder associated with NSAID treatment.